

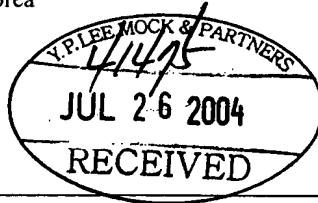
# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING

To:

LEE, Young-Pil

The Cheonghwa Building, 1571-18, Seocho-dong, Seocho-gu,  
137-874 Seoul, Republic of Korea



**PCT**

## WRITTEN OPINION

(PCT Rule 66)

|   |
|---|
| Date of mailing<br>(day/month/year) . 22 JULY 2004 (22.07.2004) |
|---|

|   |  |
|---|--|
| Applicant's or agent's file reference<br>MG-19503-PCT | <b>REPLY DUE</b> within 1 months from<br>the above date of mailing |
|---|--|

|   |   |   |
|---|---|---|
| International application No.<br><b>PCT/KR2003/001017</b> | International filing date (day/month/year)<br><b>23 MAY 2003 (23.05.2003)</b> | Priority date(day/month/year)<br>23 MAY 2002 (23.05.2002) |
|---|---|---|

International Patent Classification (IPC) or both national classification and IPC

**IPC7 A61K 38/04**

Applicant

**MOK, Kenneth Hun**

1. This written opinion is the first (first,etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I  Basis of the opinion
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When ? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d)

How ? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3  
For the form and the language of the amendments, see Rules 66.8 and 66.9

Also For an additional opportunity to submit amendments, see Rule 66.4  
For an examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis  
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 13 SEPTEMBER 2004 (13.09.2004)

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| Name and mailing address of the IPEA/KR<br>Korean Intellectual Property Office<br>920 Dunsan-dong, Seo-gu, Daejeon 302-701,<br>Republic of Korea |
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## WRITTEN OPINION

International application No.

PCT/KR2003/001017

**I. Basis of the opinion****1. With regard to the elements of the international application:\*** the international application as originally filed the description:pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the claims:pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the drawings:pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the sequence listing part of the description:pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:** contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4.  The amendments have resulted in the cancellation of:** the description, pages \_\_\_\_\_ the claims, Nos. \_\_\_\_\_ the drawings, sheet/fig \_\_\_\_\_**5.** This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

## WRITTEN OPINION

International application No.

PCT/KR2003/001017

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |        |     |     |
|-------------------------------|--------|-----|-----|
| Novelty (N)                   | Claims | 1-7 | YES |
|                               | Claims |     | NO  |
| Inventive step (IS)           | Claims |     | YES |
|                               | Claims | 1-7 | NO  |
| Industrial applicability (IA) | Claims | 1-7 | YES |
|                               | Claims |     | NO  |

**2. Citations and explanations**

D1 = US 6046168 (04.04.2000; WO 97/00890의 patent family)

D2 = US 5958885 (28.09.1999; EP 0838473의 patent family)

특허청구범위 제1항 내지 제6항은 D-Pro D-Tyr D-Val D-Val, D-Pro D-Tyr D-Val 및 D-Leu D-Thr D-Val 으로 이루어진 그룹에서 선택된 펩타이드로 이루어진 약제학적 조성물, 제7항은 D-Pro D-Tyr D-Val D-Val 또는 D-Pro D-Tyr D-Val 또는 D-Leu D-Thr D-Val로 이루어진 그룹에서 선택된 식품 조성물을 발명의 요지로 하고 있으나,

D1 문헌에 Pro Tyr Val과 Leu Thr Val으로 이루어진 약제학적 조성물과 식품 조성물, 정제, 주사제 등의 투여형태 및 투여량이 기재되어 있고,

D2 문헌에 Pro Tyr Val Val으로 이루어진 약제학적 조성물 및 식품이 기재되어 있어서, 본원의 청구항을 상기 인용 문헌들과 대비하면,

**1. 신규성**

본원의 청구항 제1항 내지 제7항은 D-Pro D-Tyr D-Val D-Val 또는 D-Pro D-Tyr D-Val 또는 D-Leu D-Thr D-Val으로 이루어진 그룹에서 선택된 약제학적 조성물 및 식품 조성을 청구하고 있으나, D1과 D2의 분리되지 않은 펩타이드 형태와 달리 D-form의 이성질체만으로 특정한 펩타이드를 청구하고 있어서 상기 청구항은 D1과 D2 문헌에 대비하여 신규성이 인정됩니다. [PCT Article 33(2)]

**2. 진보성**

본원의 청구항 제1항 내지 제7항과 인용발명들을 대비 검토하면 본원발명과 인용발명들은 혈중 트리클리세라이드 를 낮추는 펩타이드로 이루어진 약제학적 조성물을 제공한다는 점에서 목적이 동일하고, 기술적 구성에 있어서 D1문헌과 Pro Tyr Val과 Leu Thr Val의 펩타이드, 정제, 파우더, 과립, 주사제 등의 투여형태, 1 내지 100mg의 펩타이드의 구성량에서 실질적으로 동일합니다.

다만, 약제학적 조성을 및 식품 조성을 Pro Tyr Val Val의 펩타이드를 포함한다는 점과 펩타이드의 구조가 D-form으로 한정한 점에서 차이가 있으나, Pro Tyr Val Val의 펩타이드는 D2문헌의 혈중 트리클리세라이드를 낮추는 Pro Tyr Val Val의 펩타이드를 D1 문헌에 단순 채택 결합한 정도이며, 펩타이드의 구조는 본원발명에서 D-form의 광학이성질체가 L-form에 비하여 기술적 특징을 가지고 있다고 보여지지 않아 구성선택의 곤란성이 없고

또한, 이로인한 효과면에서 본원발명 Table 1에서의 D-Pro D-Tyr D-Val D-Val 과 L-Pro L-Tyr L-Val L-Val의 결과와 같이 D-form이 L-form에 대하여 예측치 못한 현저한 효과를 가진다고 보여지지 않으며 이로 인한 약제학적 조성을 및 식품조성을 당업자가 예측할 수 없는 현저한 혈중 트리클리세라이드 저하 효과를 인정할 수 없으므로 본원의 청구항 제1항 내지 제7항은 D1과 D2문헌에 의하여 진보성이 인정되지 않습니다. [PCT Article 33(3)]

**3. 산업상 이용가능성**

제1항 내지 제7항은 산업상 이용가능성이 있는 발명으로 인정됩니다. [PCT Article 33(4)]